

information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 14, 1994, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Devices and Radiological Health (21 CFR 5.53).

Dated: May 31, 1994.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 94-14315 Filed 6-13-94; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 93E-0290]

Determination of Regulatory Review Period for Purposes of Patent Extension; Reality™ Female Condom

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Reality™ Female Condom and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Reality™ Female Condom. The Reality™ Female Condom is indicated for use to help prevent pregnancy and sexually transmitted diseases, including the human immunodeficiency virus (HIV) infection, during vaginal intercourse. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for the Reality™ Female Condom (U.S. Patent No. 4,735,621) from Chartex International Plc, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated August 10, 1993, advised the Patent and Trademark Office that this medical device had undergone a regulatory review period, and that the approval of the Reality™ Female Condom represented the first commercial marketing or use of the

product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Reality™ Female Condom is 2,017 days. Of this time, 1,460 days occurred during the testing phase of the regulatory review period, while 557 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date on which the first clinical trial on the device was begun:* October 31, 1987. The clinical trial cited by the applicant was conducted outside the United States and was not subject to FDA's requirement for an investigational device exemption (IDE) under section 520(g) of the Federal Food, Drug and Cosmetic Act (the act) nor FDA's requirement for an institutional review board (IRB) approval under section 520(g) (3) of the act. Therefore, the testing phase begins on the date the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device (21 CFR 60.22(c)(1)(iii)). The applicant has stated that the date on which the device was first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device was October 31, 1987. Because of the circumstances previously described for the clinical trial cited by the applicant, FDA has no record in which to review this date (21 CFR 60.20(c)(6)). Although FDA cannot, therefore, confirm that testing began as stated by the applicant, FDA is using this date as the start of the testing phase.

2. *The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act:* October 29, 1991. FDA has verified the applicant's claim that the premarket approval application (PMA) for the Reality™ Female Condom (PMA P910064) was initially submitted on October 29, 1991.

3. *The date the application was approved:* May 7, 1993. FDA has verified the applicant's claim that PMA P910064 was approved on May 7, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 762 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before August 15, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before December 12, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 1994.

Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 94-14445 Filed 6-13-94; 8:45 am]
BILLING CODE 4160-01-F

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92-463, for the review, discussion and evaluation of individual grant applications, contract proposals, and/or cooperative agreements. These applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Panel: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Dates of Meeting: June 28, 1994.

Time of Meeting: 8 a.m. until adjournment.

Place of Meeting: Bethesda Marriott, Bethesda, MD.

Agenda: Review of Small Grant applications.

Contact Person: Dr. Mary Nekola, Scientific Review Administrator, NIDCD/SRB, Executive Plaza South, room 400C, Bethesda, Maryland 20892, (301) 496-8683.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Other Communication Disorders)

Dated: June 6, 1994.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 94-14442 Filed 6-13-94; 8:45 am]

BILLING CODE 4140-01-M

Division of Research Grants; Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meeting:

Name of SEP: Behavioral and Neurosciences.

Date: July 18, 1994.

Time: 8 a.m.

Place: Sheraton City Centre, Washington, DC.

Contact Person: Dr. Bob Weller, Scientific Review Administrator, 5333 Westbard Avenue, room 307, Bethesda, MD 20892. (301) 594-7340.

Purpose/Agenda: To review Small Business Innovation Research Program grant applications.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. (Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 6, 1994.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 94-14443 Filed 6-13-94; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-94-3739; FR-3640-N-02]

Amendment to Notice of Funding Availability (NOFA) for Comprehensive Improvement Assistance Program (CIAP)

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Amendment to notice of funding availability for fiscal year (FY) 1994.

SUMMARY: This Notice informs Public Housing Agencies (PHAs) with less than 250 units under the jurisdictions of the Houston and Ft. Worth, Texas Field Offices that the deadline date for CIAP Application submission has been extended from June 20 to July 6, 1994. Applications are due on or before 3 p.m. local time on July 6, 1994. This extension does not apply to PHAs or Indian Housing Authorities under the jurisdictions of other HUD Field Offices.

FOR FURTHER INFORMATION CONTACT: Janice D. Rattley, Director, Office of Construction, Rehabilitation and Maintenance, Department of Housing and Urban Development, 451 Seventh Street, SW., room 4140, Washington, DC 20410. Telephone (202) 708-1800; TDD (202) 708-0850. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: The CIAP NOFA, published April 19, 1994, at 59 FR 18642, stated that of the \$291,925,067 available for Public Housing CIAP, 1 percent, or \$2,919,251, had been set aside to carry out goals related to pending civil rights litigation (e.g., *Young v. Cisneros*), which is subject to judicial oversight. The Department wishes to clarify that these funds will be used to fund eligible work at the 64 CIAP eligible PHAs involved in *Young v. Cisneros*, C.A. No. P-80-8-CA (E.D. Tex.), as well as at the CIAP eligible PHA involved in *NAACP v. Housing Authority of City of Commerce*, C.A. No. CA-3-88-0154-R (N.D. Tex.). In order to give the 64 PHAs involved in *Young v. Cisneros* additional time to include in their CIAP Applications work items proposed in their revised desegregation plans submitted to the court on February 4, 1994, the Department is extending the deadline for CIAP Application submission to all PHAs under the jurisdictions of the Houston and Fort Worth, Texas Field Offices. The application deadline is